The ICS–‘BPH’ Study: the psychometric validity and reliability of the ICSmale questionnaire

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Objective To assess the validity and reliability of the ICSmale questionnaire developed for the International Continence Society–Benign Prostatic Hyperplasia (ICS–‘BPH’) study.

Reliability was assessed by measures of internal consistency and a test-retest analysis.

Results The ICSmale questionnaire was easy to complete. It was clearly able to differentiate between men in clinical and community populations, and detected the expected positive age gradient for most symptoms in the community group. There was reasonable agreement between relevant parts of the questionnaire and frequency-volume charts when a relatively flexible approach was taken, but there was a very poor relationship between questions assessing strength of stream and the results of urolflowmetry. Internal consistency was high, and overall the questionnaire demonstrated good test-retest reliability.

Conclusion The self-completed ICSmale questionnaire had high levels of psychometric validity and reliability.

Keywords Benign prostatic hyperplasia, urinary symptoms, questionnaire.

Introduction

There are currently at least six questionnaires available to researchers wishing to measure levels of urinary symptoms in middle-aged and elderly men. The style and process of the development of these questionnaires has changed markedly in the 18 years since the first was published, although their major aim, of measuring urinary symptoms quantitatively, has not. A further questionnaire, which is the focus of this paper, is currently under development within the ICS–‘BPH’ study.

The title of this study is now somewhat misplaced, as views on the use of the term BPH have changed and are changing rapidly [1]. BPH is an histological term and, as a disease process, affects 70% of men >70 years old [2]. In some patients, the gland enlarges and is termed benign prostatic enlargement (BPE). In one half of these, bladder outlet obstruction (BOO) results, termed benign prostatic obstruction (BPO). Thus, the original name of the study has been retained with the use of inverted commas and the terms defined above are used where appropriate.

The primary aim of the ICS–‘BPH’ study was to investigate the relationships between the results of high quality urodynamic studies and a wide range of urinary symptoms. Existing questionnaires measure only a limited number of symptoms, and so it was necessary to devise a new questionnaire (the ICSmale questionnaire) which contains a wide range of urinary symptoms. It is intended that this questionnaire is developed so that it may be used in research and clinical practice. This paper focuses on the validity and reliability of the ICSmale questionnaire according to standard methods of psychometric testing.

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The current range of published symptom scores

The symptom scores derived from questionnaires currently available for use in clinical studies of men with urinary symptoms are: Boyarsky [3] and Madsen—Iversen [4], the Maine Medical Assessment Program (MMAP) instrument [5], the Danish symptom score (DAN-PSS-1) [6], the AUA symptom score [7], the I-PSS (which is advocated for use by the WHO International Consultation on BPH [8] and an adapted version of the Boyarsky schedule, the Bolognese instrument [9].

Selection of symptoms

Many different symptoms are included in the various questionnaires and the process of selecting symptoms has varied considerably and has been largely arbitrary. No other questionnaire includes all possible urinary symptoms. The Boyarsky group claimed that 'BPH is a familiar and clear-cut concept ... the symptoms are clear'. [3]. Madsen and Iversen claimed that they included symptoms which were 'frequent complaints in patients'. [4]. The MMAP designed their questionnaire after discussion with urologists.[5]. The DAN-PSS-1 listed 'known symptoms of hyperplasia'. [6]. With the AUA score, symptoms were chosen from a list compiled by members of the AUA Measurement Committee', and were subjected to psychometric testing [7]. None of these scores has been validated against an objective diagnosis of BOO using urodynamic techniques.

Little evidence exists to suggest which individual symptoms are related to BPH, BPE or BPO and there is no clear concept of which groups of symptoms should be used to identify or measure patients with these conditions [8,10,11]. Interestingly, there is only one symptom which is included in all six of the scores noted above (frequency), although five other symptoms are shared by five of the six scores (weak stream, incomplete emptying, hesitancy, nocturia and intermittency). There are also several other symptoms which are included in one or more scores (dysuria, terminal dribble, straining, urgency, post-micturition dribble and incontinence of various sorts).

The developmental version of the ICSmale questionnaire contains 20 symptom questions. These were devised based on the symptoms in other questionnaires, symptoms raised by men referred to urology clinics who participated in in-depth interviews at the commencement of the study, and several other symptoms identified by urologists to be associated with lower urinary tract functioning. Thus, the ICSmale questionnaire contains symptoms associated with the storage phase, previously called 'irritative' symptoms, and the voiding phase, previously called 'obstructive' symptoms, as well as a range of other symptoms associated with the lower urinary tract, including questions related to various types of incontinence.

Method of completion

There are several important differences in how the questionnaires are completed among the scoring systems. The Boyarsky [3] and Madsen—Iversen [4] questionnaires were designed to be completed by clinicians. The MMAP instrument [5], DAN-PSS-1 [6], AUA symptom score [7], the I-PSS [8] and the Bolognese instrument [9], are all intended to be completed by patients. Self-completion questionnaires have several advantages over those completed by the clinician. They are likely to more accurately represent the patient's perception rather than the clinician's interpretation of particular symptoms. They also make it easier for patients to report the prevalence and severity of embarrassing symptoms. The ICSmale questionnaire has been designed to be completed by the patient.

Inclusion of a 'bother' factor

A new concept was introduced in the DAN-PSS-1 system; before 1991, symptom scores focused only upon the presence and severity of a symptom. DAN-PSS-1 introduced the concept of the 'bother' factor, i.e. the degree of a problem or bother that each symptom caused [6]. The AUA questionnaire also includes a set of seven 'bother' questions, corresponding to its symptom questions, although these are entirely separate.

In the ICSmale questionnaire, each question concerning the prevalence and degree of occurrence of a urinary symptom is followed immediately by a question asking about the degree of problem that it causes. This allows men to consider their experience of each symptom and then identify with some precision how much it bothers them, with responses ranging from 'no problem', through 'a bit of a problem' and 'quite a problem', to 'a serious problem.'

Quality of life and sexual function

Measurements of quality of life and sexual function are receiving increasing attention and have been important factors within the ICS—'BPH' study. The ICSmale questionnaire contains a number of questions associated with quality of life and sexual function, details of which will be published elsewhere.

Patients and methods

In the ICS—'BPH' study, 1271 consecutive men >45 years of age, attending urology departments in 12
countries, with symptoms and possible BPO were recruited between January 1992 and December 1994. Men with significant urological disease (e.g. prostate cancer), neurological disease, with previous prostatic surgery, or taking medication active on the lower urinary tract, were excluded.

Each patient was asked to complete a frequency-volume chart, detailing the times of urination during the day and night over a period of one week. Each also completed the ICSmale questionnaire, which contains 22 questions measuring 20 urinary symptoms, with 19 also assessing the degree of problem that they cause, as well as seven condition-specific quality-of-life questions and four items concerning sexual functioning. (For further details of the questionnaire, contact the authors). The questionnaire was developed in English and then professionally translated into 10 other languages. Each translation was then re-translated and checked by a lay advisor or senior urologist from each country who was nominated as a national co-ordinator for the ICS—'BPH' study. Men in the UK also completed the UK version of the SF-36 [12] and EuroQol [13], covering generic health issues, the results of which will be reported elsewhere.

As part of the study, all men were asked to void into a uroflowmeter on three occasions. The highest maximum flow rate (Qmax) was used for the purposes of the analyses presented here.

Validity and reliability

It is important that questionnaires exhibit good validity and reliability. The ICSmale questionnaire was tested for a range of types of validity:

(i) Content validity which tests whether the items in the questionnaire measure what they are supposed to measure. It is important that questions are understandable and unambiguous to the patient. In addition, the questions must be clinically sensible. These aspects were assessed through interviews with patients, by measuring levels of missing data (an indicator of inappropriate questions), and discussions with urologists.

(ii) Construct validity which relates to the relationships between the questionnaire and underlying theories. For example, there is a generally reported increase in urinary symptom scores, and some individual symptoms, with increasing age in men in the general population [14–17] and the questionnaire should be able to reflect this. Similarly, it is anticipated that men in the community have lower levels of urinary symptoms than those attending urology clinics. Thus, the distribution of symptoms across age-groups within the ICS—'BPH' study is reported, with the results of a sub-study of a population-based group of men in which all ambulant men, aged >40 years, registered with a rural general practice in the UK were invited to complete the ICSmale questionnaire (for details, see [10]).

(iii) Criterion validity which relates to how well the questionnaire correlates with a 'gold standard' measure (clinical or other validated instruments). The 'gold standard' for the measurement of BOO is pressure-flow studies (pQS). The ICSmale questionnaire was tested in relation to the results of high quality pQS, and these results will be reported elsewhere. Within the ICS—'BPH' study it is also possible to compare the results from frequency-volume diaries kept by patients against particular items in the questionnaire (frequency, nocturia). In addition, the validity of questions associated with the strength of stream was assessed in relation to the maximum flow rate achieved during the uroflowmetry.

Reliability of the ICSmale questionnaire

The reliability of a questionnaire refers to its ability to be consistent, stable and reproducible. Internal consistency was measured by statistical procedures, e.g. Cronbach’s alpha, which assesses the interrelationships of items within the questionnaire [19]. A test–retest analysis was carried out to assess the reliability of the questionnaire, in particular the stability of responses to questions over time. Clearly, a questionnaire which cannot demonstrate that its questions provoke stable responses over a short period of time in a pre-treatment sample will not be able to measure accurately changes after treatment. A sub-group of 40 patients in two UK centres was contacted by post and asked to complete a further ICSmale questionnaire at home within 2 weeks of their first questionnaire. These data have been analysed graphically and using analyses of paired differences, rather than correlations alone, which do not adequately represent agreement [20].

Results

Table 1 indicates the numbers of men recruited from each country to the ICS—‘BPH’ study. The mean age of the men was 66 years, with 254 (21%) <60 years, 512 (43%) aged 60–69 years, and 434 (36%) aged ≥70 years. The corresponding age distribution in the community sample was 63%, 22% and 14%, respectively [10].

The content validity was high; 1256 patients completed the ICSmale questionnaire, with the vast majority (94%) doing so unaided. For individual symptoms, missing data were very rare (1% to 3%).

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Table 1 Numbers of patients recruited from each country to the ICS-'BPH' study

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>47</td>
</tr>
<tr>
<td>Canada</td>
<td>35</td>
</tr>
<tr>
<td>Denmark</td>
<td>121</td>
</tr>
<tr>
<td>Germany</td>
<td>129</td>
</tr>
<tr>
<td>Israel</td>
<td>10</td>
</tr>
<tr>
<td>Italy</td>
<td>58</td>
</tr>
<tr>
<td>Japan</td>
<td>105</td>
</tr>
<tr>
<td>Netherlands</td>
<td>391</td>
</tr>
<tr>
<td>Portugal</td>
<td>49</td>
</tr>
<tr>
<td>Sweden</td>
<td>73</td>
</tr>
<tr>
<td>Taiwan</td>
<td>39</td>
</tr>
<tr>
<td>UK</td>
<td>214</td>
</tr>
<tr>
<td>Total</td>
<td>1271</td>
</tr>
</tbody>
</table>

Construct validity

Table 2 details the prevalences of individual symptoms reported by the patients in the ICS-'BPH' study and by a sample of men in the community, according to the age of the patient. As anticipated, men in the community reported lower levels of symptoms than patients in a clinical setting. Table 2 also shows that there was a general increase in the prevalence of the majority of symptoms with increasing age in the community sample, although this did not always reach statistical significance. The two sets of P-values in Table 2 are difficult to compare absolutely as the two sample sizes are very different; the age gradient needs to be much greater in the community sample to reach the same level of statistical significance as in the ICS-'BPH' patients. Hesitancy and dysuria have a negative but insignificant relationship with age in the community sample. Frequency (according to question 1: number of times per day) and the symptoms of straining to continue, incomplete emptying, post-micturition dribble, and nocturnal incontinence are similar in prevalence across the age groups.

In the ICS-'BPH' patients, the pattern was different (Table 2). Here, the general pattern of a positive association with age is not evident, except for the symptoms of nocturia and urge incontinence. On the whole, there were high prevalences of symptoms in all age groups with a general tendency to a negative association with age.

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Criterion validity

Within the ICS-‘BPH’ study, it is possible to compare responses to questions concerning frequency and nocturia with details from the frequency-volume diaries kept by patients over one week. Similarly, questions concerning urinary flow can be compared with the results of uroflowmetry.

Frequency-volume charts

A sub-sample of 79 frequency-volume charts, selected randomly across all the centres, was scrutinized in detail. A researcher (J.D.), unaware of the results of the ICSmale questionnaire, coded these charts according to the frequency of urination during the day, the time between urinations in hours, and the frequency of urination during the night (all as means over 7 days). These values were then coded so that they reflected the coding of the ICSmale questionnaire for question 1 (frequency in times per day: 1-6, 7-8, 9-10, 11-12, ≥13), question 28 (frequency in hours; hourly, 2-, 3-, ≥4-hourly) and question 2 (nocturia; not at all, once, twice, three times, four times or more). The wording of these questions is detailed in Fig. 1. After cross-tabulation of these classifications of the frequency-volume chart against the responses to the questionnaire, the proportion of individuals in the same category on both classifications was calculated giving the ‘exact’ crude agreement.

The ‘exact’ crude agreement between the frequency-volume data and question 1 (frequency in times per day) was 41%, compared with agreement of 61% for question 28 (frequency in hours between urinations). The ‘exact’ agreement for question 2 (nocturia) was 68%. The corresponding Kappa values were 0.20, 0.27 and 0.57, respectively, indicating at best a ‘fair’ agreement for the frequency questions, but better (‘moderate’ to ‘good’) agreement for nocturia [18].

If the criteria for agreement are widened to allow a discrepancy of plus or minus one category, these agreements rise to 91% (question 1), 99% (question 28) and 97% (question 2).

Uroflowmetry

Patients were asked to void into a flowmeter three times: 47% voided three times, 36% twice and 17% once (n = 1190). Two questions in the ICSmale questionnaire address the issue of reduced stream (see Fig. 1).

Question 12 asked men to judge whether the strength of their urinary stream was ‘normal’ or ‘reduced occasionally’, ‘sometimes’, ‘most of the time’ or ‘all of the time’. Question 14 asked the men to indicate their flow rate on a diagram of a man urinating (4 indicating very reduced, to 1 indicating a ‘normal’ flow). Clearly, neither of these questions allowed a direct comparison with the flow rates recorded on uroflowmetry. However, it was possible to determine whether men with a low flow rate recorded a reduced stream on questions 12 and 14. Table 3 shows clearly that there was a very weak relationship between the perception of low flow and objective data from uroflowmetry when patients were categorized above or below a Qmax of either 10 mL/s or 15 mL/s.

Reliability

Internal consistency For the basic set of symptom questions (20 in total), and problem questions (19 in total), the Cronbach’s alpha statistics were high, at 0.84 and 0.91, respectively. These high scores are partly a reflection of the large number of items, but also show that these parts of the questionnaire have excellent levels of internal consistency. The Cronbach’s alpha statistic for the storage symptoms was 0.69, for the voiding symptoms 0.75, and for the other symptoms 0.69. For the problem questions it was 0.82 (storage), 0.85 (voiding), and 0.75 for the other problems.

Test-retest reliability For seven symptom questions and 11 problem questions there was excellent test–retest reliability, with a maximum difference of one category between the time points (e.g. from ‘occasionally’ to ‘sometimes’). For the other questions, some had larger discrepancies, but typically these were for only one individual of the 40 studied. The reliability of the six most common urinary symptoms and problems is portrayed graphically in Figs 2 and 3. In Fig. 2, reduced stream, terminal dribble and nocturia were the most reliable of the common symptom questions, with none or only one patient moving more than one category between the time points. Incomplete emptying,
1. During the day, how many times do you urinate, on average?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 6 times</td>
<td>Not a problem</td>
</tr>
<tr>
<td>7 to 8 times</td>
<td>A bit of a problem</td>
</tr>
<tr>
<td>9 to 10 times</td>
<td>Quite a problem</td>
</tr>
<tr>
<td>11 to 12 times</td>
<td>A serious problem</td>
</tr>
<tr>
<td>13 or more times</td>
<td></td>
</tr>
</tbody>
</table>

How much of a problem is this for you?

None  | Getting up 1 time  | Getting up 2 times  | Getting up 3 times  | Getting up 4 or more times

How much of a problem is this for you?

None  | Getting up 1 time  | Getting up 2 times  | Getting up 3 times  | Getting up 4 or more times

How much of a problem is this for you?

None  | Occasionally reduced | Sometimes reduced | Reduced most of the time | Reduced all of the time

How much of a problem is this for you?

None  | Occasionally reduced | Sometimes reduced | Reduced most of the time | Reduced all of the time

How much of a problem is this for you?

Normal  | Occasionally reduced | Sometimes reduced | Reduced most of the time | Reduced all of the time

How much of a problem is this for you?

Normal  | Occasionally reduced | Sometimes reduced | Reduced most of the time | Reduced all of the time

How much of a problem is this for you?

Normal  | Occasionally reduced | Sometimes reduced | Reduced most of the time | Reduced all of the time

How much of a problem is this for you?

28. How often do you pass urine during the day?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hourly</td>
<td>Not a problem</td>
</tr>
<tr>
<td>Every 2 hours</td>
<td>A bit of a problem</td>
</tr>
<tr>
<td>Every 3 hours</td>
<td>Quite a problem</td>
</tr>
<tr>
<td>Every 4 hours or more</td>
<td>A serious problem</td>
</tr>
</tbody>
</table>

How much of a problem is this for you?

Hourly  | Every 2 hours  | Every 3 hours  | Every 4 hours or more

How much of a problem is this for you?

Hourly  | Every 2 hours  | Every 3 hours  | Every 4 hours or more

How much of a problem is this for you?

From Peeling, 1989[22]

Fig. 1 Wording of selected questions and responses in the ICSmale questionnaire

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intermittency and hesitancy were less reliable, with between two and five patients moving more than one category. Amongst the questions about problems (Fig. 3), all except reduced stream were highly reliable.

Simple additive scores were computed for the questionnaire to assess further the test–retest reliability. The overall Spearman rank correlation coefficient for this symptom score between the time points was 0.78 (95% CI: 0.62 to 0.88); for this problem score it was 0.83 (95% CI: 0.70 to 0.91).

Discussion

The process of testing for validity and reliability of questionnaires available for use in BPH has varied widely. Little validation has been carried out in any formal sense for the Boyarsky or Madsen–Iversen scores. The MMAP instrument has had some validation in relation to changes in scores before and after treatment [5]. The assessment of validity and reliability in terms of psychometric testing (e.g. formal comparisons of urology...
patients and non-urology patients) has been carried out on the AUA [7], DAN-PSS-1 [6] and Bolognesi[9] symptom scores. This paper reports similar investigations for the ICsmale questionnaire.

The ICsmale questionnaire was designed to be self-completed and the majority of ICs-'BPH' patients and men in the community [10] found it easy to complete in full and unaided. In-depth interviews with men carried out by one of the authors (J.D.) during the piloting of the questionnaire indicated that men found the questions and response categories easily understandable. The results in the present study indicate that the questionnaire has high levels of acceptability. National co-ordinators for the study have indicated that the questionnaire covers all appropriate symptoms. Overall, therefore, the ICsmale questionnaire has a high level of content validity.

The ICsmale questionnaire detected the expected positive age gradient for the majority of urinary symptoms in the community sample. The symptoms showing the strongest positive relationships with age in the community sample (nocturia and urge incontinence) were also positively related to age in the ICs-'BPH' patients. In part, the increasing prevalence of nocturia reflects the increasing occurrence of nocturnal polyuria secondary to covert cardiac failure [21], whereas the increase in urge incontinence is probably due to the strong relationship between detrusor instability and age [8]. The relationships of other symptoms with age for the ICs-'BPH' patients are either non-existent or even negative. This is likely to be largely because the patient group is self-selecting according to the level of symptoms.

The ICsmale questionnaire was able to differentiate clearly between men in the community and a sample derived from a clinical population. Higher levels of symptoms were evident in the ICs-'BPH' patients and, amongst those with symptoms, the ICs-'BPH' patients considered them to be bothersome much more frequently than those in the community sample [10]. In combination with the results concerning age, this suggests that the ICsmale questionnaire has good construct validity.

The poor exact agreement between the data from the frequency-volume charts and the questions on urinary frequency and nocturia has a variety of possible explanations. It is perhaps unreasonable to expect an unprepared patient to categorize their urinary frequency accurately and within the constraints of a questionnaire. Further, in the frequency-volume charts studied, many patients reported different levels of frequency from day to day, thus adding to the difficulty in specification. It is also possible that patients' experiences over the previous day or two will influence their report or that they may subconsciously over-estimate their symptoms.

Importantly, however, there was considerably better agreement between the results of the frequency–volume charts and the questionnaire when a slightly more flexible approach was taken.

It is possible from these analyses to choose between the questions concerning frequency in the developmental version of the ICsmale questionnaire. Specifically, question 28 (frequency in hours between urinations) has a higher level of validity in relation to the frequency volume charts than does question 1 (frequency according to the number of times per day). A definitive choice awaits the results of analyses of symptoms in relation to pQ8 (papers in preparation).

The results indicate that there was very little relationship between the men's perception of their stream being reduced and the uroflowmetry data (represented by their highest flow). There may be several reasons for this, e.g. the men's normal experience of flow may not be reproduced by the artificiality of voiding into a flowmeter in a clinical setting. It may also be that the men's reporting of their flow rate is most likely to be based on their own experience of their flow rate, and so the perception of what is normal and abnormal is probably quite variable between individuals and not necessarily related to what is measured on uroflowmetry. Clearly, a man who has previously had a very high flow rate may perceive it to be reduced, but it may remain more than 15 mL/s. It may also be that the wording of question 12 and the figure in question 14 do not manage to capture accurately the men's perceptions of their flow rate. It is clear that neither of these questions in their present form relates closely to free-flow rates. It is also the case that the patient may be assessing the whole of micturition, not just the Qmax from the uroflowmetry considered in this analysis.

The internal consistency (as measured by Cronbach's alpha) of the ICsmale questionnaire was very high. The values given are very similar to those reported for the AUA score overall and for storage and voiding symptoms [7]. The results for the ICsmale questionnaire also indicate that internal consistency is not improved by dividing the questionnaire into the arbitrary assignment of storage and voiding symptoms.

It is particularly important that a questionnaire likely to be used for assessing outcome is stable at baseline, otherwise it will be difficult to interpret changes following an intervention. This was assessed for the ICsmale questionnaire by a test–retest analysis. Given the high correlations of scores and, more pertinently, the high proportions of men with the same symptom assignments on both occasions, the results indicate that the ICsmale questionnaire is highly reliable.

In conclusion, the ICsmale questionnaire has high levels of psychometric validity and reliability. It is now
possible and necessary to examine the relationships between responses to this wide-ranging questionnaire and the results of pressure-flow studies.

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